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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER
FORD, JOHN M

ART UNIT	PAPER NUMBER
1624	

DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/986,725	Jensen et al
Examiner	**Group Art Unit**
T.M. Ford	1624

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

☒ Responsive to communication(s) filed on Feb 10, 2003.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☒ Claim(s) 1, 3--21, 26--32 and 34 is/are pending in the application.

Of the above claim(s) 20, 21 and 27--32 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) 1, 3--19, 26 and 34 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement

Application Papers

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119 (a)-(d).

☐ All ☐ Some* ☐ None of the:

☐ Certified copies of the priority documents have been received.

☐ Certified copies of the priority documents have been received in Application No. _____.

☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a))

*Certified copies not received: _____.

Attachment(s)

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

Applicants response of Feb. 10, 2003 is noted.

The claims in the application are claims 1, 3--21, 26--32 and 34.

Claim 1 is rejected under 35 U.S.C. 112, 2nd paragraph. The phrase "poly-heterocyclic" is not clear as to its meaning. It is suggested that claim 3 be combined with claim 1 to clear up what is intended by aryl, polycyclic aryl, mono or poly-heterocyclic.

Claim 3 is rejected because it is dependent on a rejected claim.

The phrase "selective Ikca modulatory activity" in claim 1 is a laboratory test, it is not a real world disease. Claim 1 is rejected under 35 U.S.C. 112, 1st paragraph.

The recent utility guidelines set by USPTO require applicants to meet the requirements as stated in Brenner v. Manson in 148 USPQ 689, which requires that utility be developed to a point where "specific benefits exist is currently available form", similar is the "immediate benefit to the public: standard set forth in the concurring opinion of In re Hartop, 135 USPQ 419; "whether the invention has been brought to such perfection as to be capable of practical employment", this language is echoed in Bindra vs Kelly, 206 USPQ 570.

This requirement of one specific utility is consistent with 37 CFR 1.475; the Unity of Invention Practice in International Applications and National Phase Applications under 35 U.S.C. 371, and PCT Rule 13.2.

Therefore, applicants should limit the method claims to a sole "specific utility".

Applicants need to pick <u>one</u> believable utility for the claims.

Examples of generalized and vague assertions of utility which do not meet the disclosure requirement of 35 U.S.C. are: statement that a product is a pharmaceutical", "therapeutic agent", or has "biological utility", or is "an intermediate to make a drug", citing, respectively, In re Diedrich (CCPA 1963) 318 F2d 946, 138 USPQ 128; In re Lorenz et al. (CCPA 1962) 305 F2d 875, 134 USPQ 312 and Ex parte Brokman et al. (POBA 1959) 127 USPQ 57; In re Kirk et al. (CCPA 1967) 153 USPQ 48; and In re Joly et al. (CCPA 1967) 376 F2d 906, 153 USPQ 45.

A disclosure that the claimed compounds can be used for "technical and pharmaceutical purposes" does not met the requirements of 35 U.S.C. 112, In re Diedrich (CCPA 1963) 318 F2d 946, 138 USPQ 128.

The expressions "biological activity" and "biological properties" are too nebulous to meet the requirement of 35 U.S.C. 112. In re Kirk et al. (CCPA 1967) 376 F2d 936, 153 USPQ 48. Same, "good effects against a very wide ring of insects". In re Lorenze et al. (CCPA 1962) 305 F.2d 875, 134 USPQ 312.

The "how to use" requirements of 35 U.S.C. 112 are not met by disclosing only a pharmacological activity of the claimed compounds if one skilled in the art would not be able to use the compounds effectively without undue experimentation. In re Driedrich (CCPA 1963) 318 F.2d 946, 138 USPQ 128; In re Gardner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138. Thus, where the claimed compounds are not structurally similar to known compounds having the same activity and their pharmaceutical properties could not be predicted their chemical structure, a disclosure that they possess a particular activity against a pathological organism (antitubercular

activity) may not suffice as a description of how use as required by 35 U.S.C. 112. In re Moureu et al. (CCPA 1965) 345 F2d 595, 145 USPQ 452.

Statements of utility which relate to or imply the treatment of a disease are subject to closer scrutiny. Ex parte Moore et al. (POBA 1960) 128 USPQ 8. Thus, when the disclosed utility is the production of a physiological response, e.g. antidepressant effect, the dosage effective to achieve this response in host, whether human or animal, must be disclosed. In re Garner et al. (CCPA 1970) 427 F2d 786, 166 USPQ 138.

The fact that structurally unrelated prior art compounds have been used to protect he liver fro the effects of hepatitis does not render obvious to one skilled in the art how to use a novel compound disclosed to "assist the liver Function in hepatic disturbances and can, therefore, be used as medicament in humans and veterinary medicine". In re Schmidt et al. (CCPA 1967) 377 F2d 639, 153 USPQ 640.

A specification which discloses only one mode of administration of medicinal for the purpose of effecting a modification in a body function does not provide support for a claim not limited to that specific mode. Ex parte Proctor (POBA 1966) 158 USPQ 677.

A method claim which designates amount of an ingredient of a claimed method as "an effective amount" is too broad and indefinite if it does not designate the intended effect; Ex parte Dobson et al. (POBA 1969) 165 USPQ 29. In re Fedriken, 102 USPQ 35, (CCPA 1954) A cancer or a tumor, or a solid tumor is not specific to one disease.

Issentstead v. Watson, (DCDC 1957) 157 F Supp. 7, 115 USPQ 408 and Schindler v. Comr. of Pats. (DCDC 1967) 269. F. Supp 630, 155 USPQ 838. Note where an application discloses therapeutic effect on humans or a cure for a human disease as the utility of a claimed process, the District Court held that proof of such utility is required unless one of ordinary skill in the art would accept the utility statement as obviously valid and correct. Radoev v. Brenner, Ferguson, (POBA 1957) 117 USPQ 229.

Where utility is based on the alleged enhancement of activity of known medicinals. The CCPA up held Examiner's requirement that the applicant submit evidence which substantiated the allegation, unless one skilled in the art would accept then as obviously valid and correct. In re Novak et al., (CCPA 1962) 306 F2d 924, 134 USPQ 335.

The Board of Appeals and the CCPA have held that even though the specification does not mention human use specifically, the Patent Office is not precluded from finding an inference of human use and require proof thereof when such use is a medical nature for the treatment of a serious disease, such as cancer. Ex parte Moore et al., (POBA 1960) 128 USPQ 8; In re Citron (CCPA 1964) 325 F2d 248, 139 USPQ 516; In re Hartop et al., (CCPA 1962) 311 F2d. 135 USPQ 419.

The Supreme Court declined to expresses a view as to whether patentability can be based on a product shown to inhibit the growth of tumors in laboratory animals. Brenner, Comr. pats. V. Manson, (USC 1966) 383 U.S. 519, 148 USPQ 689. The Court did state, however, that Congress did not intend that a patent on a chemical compound, or a process for its production, whole sole "utility" consists of its potential role as an object of use-testing, reasoning the patent

system is related to the World of Commerce, rather than the realm of philosophy ibid., 148 USPQ at 696.

The utility of a process for producing remissions in patients suffering from chronic myeloid leukemia was established by clinical reports and data, the acceptance of the drug employed by the Food and Drug Administration and by and American Medical Association Council on Pharmacy, the Board noting that remission, not cures, were alleged in the specification. Ex parte Timmis, (POBA 1959) 123 USPQ 581. Evidence involving a single compound and two types of cancer, was held insufficient to establish the utility of claims directed to a method of treating seven cancers. In re Butting , (CCPA 1969) 418 F2d, 163 USPQ 689.

Claims 1 and 4 are rejected under 35 U.S.C. 112, 1st and 2nd paragraphs.

What is intended by aryl, polycyclic aryl, heterocyclic and poly heterocyclic group in Ar?

Heterocyclic is a huge area of Chemistry, that completely overshadows the formula I or II.

The heterocyclic term is not set forth in the claim in clear, specific language. The reader must produce the heterocyclic ring, in question.

Judge Smith noted many different definitions for aryl in the footnotes of In re Sus, 134 USPQ 301. It, therefore, becomes necessary for applicants to indicate in the claims what they intend by aryl. Heterocyclic, likewise, means many different things to different people. Some definitions of heterocyclic include B, P and As as hetero atoms. The U.S.P.T.O. does not consider

those heterocyclic, and does not classify those patents as hetero rings. What applicants intend need be found in the claim.

The specification serves various purposes, it sets forth the prior art, that which applicants found unsuccessful, a defensive publication, that which applicants decided not to claim, or compounds that step the infection, but kill the patient. The reader cannot tell the extent of the new invention, unless it is clearly set forth in the claims, out of the mixed pieces of information of the specification. The claims have to clearly set out that which is claimed.

The heterocyclic term is not acceptable, as it reads on heterocyclic rings that require specific conception by the reader. Specific, producible, heterocyclic rings are not set forth in the claims. The source of the staring materials for the combinations claimed is not set forth.

Exactly what ring is being claimed must be set forth in the claim.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

Where is, what is intended by applicant, supported in the specification with sufficient representative exemplification? Note United Carbon Co. vs. Binney Smith Co. 55 U.S.P.Q. 381, Supreme Court of the United States (1942) "an invention must be capable of accurate definition, and it must be accurately defined to be patentable", above at 386.

Assuming that applicant is claiming what he regards as his invention, there are in reality only two basic groups for rejecting claims under 35 U.S.C. 112; first is that language used is not precise enough to provide a clear-cut indication of scope of subject matter embraced by claim;

this ground finds its basis in second paragraph of section 112; second is that language is so broad that it cause claim to have a potential scope of protection beyond that which is justified by specification disclosure; this ground stems from first paragraph of section 112, merits of language in claim must be tested in light of these two requirements.

The heterocyclic variable is not precise and definite enough to provide a clear-cut indication of the scope of the subject matte embraced by the claim. The heterocyclic concept is so broad that cause the claim to have a potential scope of protection beyond that which is justified by the specification disclosure.

The written description is considered inadequate here in the specification. Conception should not be the role the reader. Applicants should, in return for a 17/20 year monopoly, be disclosing to the public that which they know as an actual demonstrated fact. The disclosure should not be merely an invitation to experiment. This is a 35 U.S.C. 112, first and second paragraph rejection. If you (the public) find that it works, I claim it, is not a proper basis for patentability, In re Kirk, 153 U.S.P.Q. 48 at page 53.

The heterocyclic rings possible is wide open to staggering possibilities.

Applicants place too much conception with the reader. The heterocyclic expression leaves open which one: Azines, Diazine, Triazines, Tetrazines. Where are the starting materials in the specification? Adjacent O and S are too strained to be produced.

Conception of what the intended heterocyclic ring, may be, should not be left to the reader.

One needs to know exactly where, in the ring, the hetero atoms are: 1,2, or 1,3 or 1,4 or 1,2,4, or 1, 3, 4, etc., as each is a different entity, with a separate search.

One, on reading the indication of heterocyclic applied by applicant, has no idea where the hetero atoms are in this unknown ring,.

What are the hetero atoms?

Not all heterocyclic rings have been shown to be producible, as stable, at room temperature. What is the source of the starting materials? Where is the adequate representative exemplification in the specification to support the claim language?

The heterocyclic term presents a problem of lack of clear claiming, and support in the specification for the variables sought.

This rests conception with the reader.

What exactly is intended, and where is that supported in the specification. Note a fair burden in return for applicants receiving a 17/20 year monopoly.

The possible combinations of any number of hetero atoms, in any combination, in multiple size rings is quire large, and not shown by applicants to be available starting materials.

A Markush listing of intended, conceived of, producible, heterocyclic rings is what is needed here. It is not possible to classify and search the molecule unless one knows exactly which heterocyclic ring is being claimed.

The ultimate utility here is a pharmaceutical use. Declarations of unexpected results are often presented in the pharmaceutical arts. Applicants breadth of hetero cyclic produces many

different heterocyclic rings that could easily affect results. This is already a sensitive area of utility.

Applicants need to claim what they have demonstrated as a specific fact.

The heterocyclic expression in claim 1 are not acceptable, as they do not indicate, exactly, clearly, and specifically, what heterocyclic ring is being claimed. These expressions rest specific conception with the reader, and the specification does not include the source of the starting materials for the rings which applicant now claims. One must be able to tell from a simple reading of the claim what it does and does not encompass.

It is suggested that claim 5 be combined with claim 4.

The claims measure the invention, United Carbon Co. v.s. Binney & Smith Co., 55 U.S.P.Q. 381 at 384, col. 1, end of first paragraph, Supreme Court of the United States (1942).

The U.S. Court of Claims held to this standard in Lockhead Aircraft Corp. v.s.. United States, 193 U.S.P.Q. 449, "Claims measure the invention and resolution of invention must be based on what is claimed".

The CCPA in 1978 held "tat invention is the subject matter defined by the claims submitted by the applicant". "We have consistently held that no applicant should have limitations of the specification read into a claim where no express statement of the limitation is included in the claim": In re Priest, 199 U.S.P.Q. 11, at 15.

The heterocyclic expression includes adjacent O/S combinations that are unstable. That open ended breadth cannot be allowed. The claim cannot be completely searched, here, until we

know what applicants intended by heterocyclic, see In re Wiggins; 179 USPQ 421. Where is the support in the specification?

Similarly, the USPTO only recognizes: C ,N,O,S,Se or Te as atoms of a heterocyclic ring. Therefore, there is need for applicants to indicate what they mean by heterocyclic.

Heterocyclic is not just a substituent; it is a whole body of art,

Researchers often spend their entire life on hetero N heterocyclic compounds, without ever getting to hetero O or hetero S compounds. Many heterocyclic compounds, within the claim, have never been made.

Claim 5 is rejected, as being dependent on a rejected claim.

Claim 6 is rejected for the reasons claim 1 and 4 were rejected; the resolution being to combine claim 7 with claim 6.

Claim 8 is rejected as above, for the reasons claims 1 and 4 were rejected; the resolution being to combine claim 9 with claim 8.

Claim 9 is rejected as it is dependent on a rejected claim 1.

Claim 10 is rejected for the reasons claims 1 and 4 were rejected.

The resolution being to combine claims 10 and 11.

Claim 11 is rejected a being dependent on a rejected claim.

Claims 12, 14, and 16 are rejected for the reasons claims 1 and 4 were rejected.

Claims 13, 15 and 17 are rejected as being dependent on a rejected claims.

Claims 18 and 19 are rejected to as being dependent on a rejected claim.

MPEP 806.05(h) provides for restriction where the compounds may be used for more than one purpose. Claim 19 becomes an evidence claim to that allegation. Applicants need to pick one demonstrate able use.

There is undue experimentation in regard to claim 19 to determine what host-dosage information would be required to produce each result. Many of the diseases in claim 19 are too broadly stated to meet the requirements of 35 U.S.C. 112.

Now, what of claim 20, 21 and 31? The agreement to examine one use of the compounds with the compounds is based on their being the same scope. Claims 20, 21 and 31 have additional active ingredient. Therefore, they are not the same scope, and stand withdrawn as being directed to another invention.

Claim 26 is rejected as it is dependent on a rejected claim.

Claims 27--30 and 32 are drawn to multiple unestablished uses of the compounds. MPEP 806.05(h) provides for restricting these claims out, altogether, where applicants have not elected one demonstrate able use for the compounds. Claims 17--30 and 32 are held withdrawn, as the claims themselves allege more than one use of the compounds, and become evidence claims to that allegation.

The compound of claim 34 is found in col. 21 of U.S. Patent 6,028,103. Therefore, claim 34 and claim 1 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. Patent 6,028,103. See col. 3, lines 15--20 and col. 8, lines 55--60, of that Patent. Since, such a range of uses are alleged for claim 34, here, method is obvious from the prior art.

John M. Ford:jmr

March 17, 2003

JOHN M. FORD
PRIMARY EXAMINER
GROUP - ART UNIT 1624

The Examiner John M. Ford can normally be reached Monday--Friday 8:30--5:00 at 703-308-4721.

The Fax number is 703-308-4734.